

EXHIBIT D



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/209,276	08/12/2011	Ian Kitching	83289-814686 (015320US)	9760
107046	7590	11/20/2012	EXAMINER	
WSGR / Align Technology , Inc. 650 Page Mill Road Palo Alto, CA 94304			SEWARD, MATTHEW JOHN	
			ART UNIT	PAPER NUMBER
			3732	
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			11/20/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	13/209,276	KITCHING ET AL.	
	Examiner	Art Unit	
	Matthew Seward	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 July 2012.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) Claim(s) 1 and 43-68 is/are pending in the application.
 - 5a) Of the above claim(s) 51-68 is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 1 and 43-50 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some
 - * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/27/2012.
- 3) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 4) Other: _____.

DETAILED ACTION

Claim 1 is currently amended. Claims 2-42 are cancelled. Claims 43-68 are newly added. Claims 51-68 are withdrawn by the examiner. Claims 43-68 are pending.

Election/Restrictions

Newly submitted claims 51-68 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 51-59 are directed to a system for staging the movement of a plurality of dental objects. The system as claimed is capable of use in a materially different method.

Claims 60-68 directed to a machine-readable storage medium. The method of claim 1 can be practiced without a storage medium, and the storage medium can be used in a materially different process. Therefore claims 60-68 are patentably distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 51-68 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Information Disclosure Statement

Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in

Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 43-50 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A claim is deemed to be unpatentable as directed to non-statutory subject matter if:

1. The claimed invention is not directed to one of the four categories of statutory subject matter; OR
2. The claimed invention is wholly directed to subject matter encompassing a judicially recognized exception.

Claims 1 and 43-50 are directed to a process, but contain subject matter that is wholly directed to an abstract idea, the method of staging the movement of a plurality of dental objects.

Claims 1 and 43-50 are directed to a method that is performed for "staging the movement of a plurality of dental objects." Claim 1 recites three steps, two steps involving the transmission of electronic representations to a host computer. These steps involve only the receipt of a transitory electrical signal by a host computer. The final

steps involves a calculation by the host computer that determines "an order of movement for each respective dental object."

The scope of claim 1 is broad, and does not require the use of a specific machine, as the claim requires only that the steps be performed "by a host computer." The mere inclusion of a host computer does not adequately specific nor provides a meaningful limitation of the claim. Further, there is no particular article that is transformed in carrying out the steps of the claimed method. Therefore, it is determined that the recitation of the host computer is insufficient to direct the claim to statutory subject matter as the computer is merely an object on which the method operates. The significant acts of the method can be performed entirely in the mind.

As the inclusion of the general-purpose host computer is insufficient to provide a meaningful limitation to the claim, the claim covers substantially every practical application of a method for staging the movement of a plurality of dental objects.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):

(B) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 43-50 rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly

claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Claim 1 requires the calculation of "an optimal number of stages." However, it is unclear what may be considered an "optimal number" of stages in orthodontic treatment. The number of stages represents a compromise between treatment time and patient comfort, taking into account the maximum force than can be applied to the various types of teeth. Because of this, and individual patient tolerances for pain, the "optimal number" of stages may be considered the shortest treatment time possible, the shortest treatment time with significant patient comfort, the shortest treatment time for specified force levels for individual teeth, etc. Therefore, the claim is indefinite as it is not clear what is "optimal" as it is a term of degree as applied to orthodontics.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 5 of prior U.S. Patent No. 8,038,444 (hereinafter the '444 patent).

This is a double patenting rejection.

Claim 1 contains the same subject matter as claim 5 of the '444 patent. The differences between the two claims are the replacement of "desired final" with "corrected," and the addition of the limitation "each dental object being in a respective initial position." These differences do not alter the scope of the claim. The replacement of the "desired final position" to a "corrected position" are both names given to represent the position of the tooth at the end of treatment. These terms are used interchangeably in the specification of the '444 patent and the present application, see col. 2, lines 6-8 of the '444 patent. The terms represent the same concept and have the same scope. The limitation "each dental object being in a respective initial position" was added to provide antecedent basis for the limitation "initial position" in line 10 of claim 1. Therefore, the scope of claim 1 is entirely coextensive with the scope of claim 5 of the '444 patent.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 43-46 and 48-50 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4 and 12-14 of the '444 patent.

Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 43-45 contain the same subject matter of claims 2-4, respectively, of the '444 patent. The only difference between claims 43-45 and claims 2-4 of the '444 patent is the inclusion of two limitations: (1) "each dental object being in a respective initial

position" and (2) "an optimal number of stages is calculated for the order of movement for each respective dental object."

As previously discussed, limitation (1) does not alter the scope of the claim. Limitation (2) is also present in the '444 patent in claim 5. This difference is not deemed to patentably distinguish the claims of the present application from claims 2-4 of the '444 patent, as the inclusion of the step of calculating an optimal number of stages for the order of movement for each respective dental object, as taught by claim 5 of the '444 patent, would have been obvious to one of ordinary skill in the art at the time the invention was made, as the calculation of a desired or optimal number of stages is known in the art of orthodontic planning.

Claims 46 and 48-50 are identical in scope to claims 6 and 12-14 of the '444 patent, the only difference between the claims arising from their dependency on claim 1, which includes limitation (2). This difference does not patentably distinguish the present claims from claims 6 and 12-14 of the '444 patent for the reasons discussed regarding claims 43-45.

Claim 47 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of the '444 patent, in view of Chishti et al. (US 2004/0137400).

Claim 47 is coextensive in scope with claim 5 of the '444 patent. The only difference between the claims is the inclusion of "determining a schedule for moving

each dental object in the plurality of dental objects" in the step of determining the order of movement.

Chishti teaches another computer-implemented method for staging the movement of a plurality of dental objects including determining a schedule for moving each dental object in the plurality of dental objects (see [0122], [0137-0138], Figs. 11-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include determining a schedule for moving each dental object in the plurality of dental objects as determining a schedule for orthodontic appliances-mediated tooth movement is common practice in orthodontics and well within the level of ordinary skill in the art. This does not render claim 47 patentably distinct from claim 5 of the '444 patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 43-45, 47, 48 are rejected under 35 U.S.C. 102(b) as being anticipated Chishti et al. (US 2004/0137400 A1).

Chishti discloses a computer-implemented method for staging the movement of a plurality of dental objects (abstract, [0004]), including receiving, at a host computer, an

electronic representation of each dental object of the plurality of dental objects in relation to one another, each dental object being in a respective initial position (initial position, [0055-0056]), receiving, at a host computer, an electronic representation of a corrected position for each respective dental object ([0057]), determining, by using the host computer, an order of movement for each respective dental object (see Fig. 11, illustrating movements for individual teeth) such that the dental objects avoid colliding with or obstructing each other on their respective routes from the initial position to their respective corrected position through staggering of at least two dental objects (Fig. 11, [0151], the posterior teeth are delayed from moving for multiple stages in a way that will prevent the posterior teeth from colliding with the adjacent tooth in the anterior direction), and an optimal number of stages is calculated for the order of movement for each respective dental object ([0090-91]),

determining a route that each respective dental object will move to achieve its respective corrected position ([0137]), the distance each respective dental object will move to achieve its respective corrected position ([0146]), the rate at which each respective dental object will move along its respective route ([0136]), the route, distance and rate are determined in relation to each of the other dental objects (e.g. [0146]; the operation of the software to provide visualization of the treatment stages to a user requires a calculation that determines the route, distance and rate of each object),

adjusting the route or rate of at least one dental object to avoid collision with another dental object ([0120]),

the step of determining the order of movement steps includes determining a schedule for moving each dental object in the plurality of dental objects ([0138]), determining the order of movement includes slowing the movement of at least one dental object ([0116]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chishti.

Chishti discloses a computer-implemented method including determining a total distance each respective dental object will move (the distance between the final position and the initial position, see [0136]),

determining a number of movement stages for each dental object ([0013], “The method can include dividing a path for one or more teeth into the series of stages while keeping the movement of teeth in each stage below a predetermined range”), determining a number of non-movement stages for each respective dental object (see Fig. 11, each individual object has a number of non-movement stages), determining a number of stages for each respective object ([0017]).

Chishti does not disclose dividing the total distance for each dental object by its respective maximum speed to determine the number of movement stages, adding the number of movement stages to the number of non-movement stages for each dental object to determine the minimum number of stages for each object, and selecting the largest of the minimum number of stages.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Chishti to include dividing the total distance for each dental object by its respective maximum speed to determine the number of movement stages, adding the number of movement stages to the number of non-movement stages for each dental object to determine the minimum number of stages for each object, and selecting the largest of the minimum number of stages, as these details of the method represent nothing more than basic arithmetic one uses to count the minimum number of stages and selecting the number of stages based upon the slowest moving object in the group, or the rate-limiting step. Simple arithmetic and the knowledge that the process can only proceed as fast as the rate-limiting step amount to common sense well within the level of ordinary skill in the art.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chishti in view of Chishti et al. II (US 6,682,346 B2).

Chishti discloses a method substantially as claimed, but does not disclose the step of determining the order of movement including round tripping at least two dental objects.

Chishti II teaches a method of dental treatment planning including round-tripping (col. 4, lines 21-28).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Chishti to include round tripping two teeth, when necessary, as taught by Chishti II, in order to move the teeth in the quickest fashion while avoiding collisions.

Response to Arguments

Applicant's arguments filed 07/27/2012 have been fully considered but they are not persuasive.

Regarding the rejection under 35 U.S.C. 101, applicant states that claim 1 is not wholly directed to an abstract idea. The examiner respectfully disagrees. The subject matter for which applicant seeks to obtain a patent, is directed to the general concept or abstract idea of orthodontic planning, as clarified in the present Office Action. Applicant can overcome the 101 rejection by including a step in which a product is produced, such as the orthodontic appliances discussed in [0024] of the original specification.

Applicant states that the amendments to claim 1 are sufficient to overcome the rejection under Chishti. The examiner disagrees, Chishti discloses a computer-implemented method including using the host computer to determine an optimal number of stages for the order of movement for each respective dental object. This is demonstrated in the text of Chishti in paragraphs [0090-91] which discuss the maximum amount of movement distance that occurs in each treatment stage. The treatment plan is calculated using this maximum movement distance (0.25-.33 mm for each 2-week stage), which is a determination of the optimal number of stages. One of the central focuses of orthodontic treatment planning minimizing the amount of time required to safely reach a desired outcome.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew Seward whose telephone number is (571)270-5090. The examiner can normally be reached on Monday to Friday 9:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571)-272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Matthew Seward/
Examiner, Art Unit 3732

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732